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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,726	03/13/2006	Anke Klippel-Giese	39078-0009US1	2321
26633	7590	07/12/2007		
HELLER EHRMAN LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			EXAMINER SCHNIZER, RICHARD A	
			ART UNIT 1635	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,726	Applicant(s) KLIPPEL-GIESE ET AL.	
	Examiner Richard Schnizer, Ph. D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

As an initial matter, it is noted that claims 34-60 appear to be misnumbered. This application was filed under 35 USC 371. During prosecution of the parent PCT application, an Article 34 amendment was filed containing 26 claims, replacing original PCT claims 1-33. So, the national stage application was filed on 4/18/05 with 26 claims. A preliminary amendment was also filed on 4/18/05 canceling "Claims 1-33" and adding claims 34-60. Claims 34-60 are pending in this application. However, these claims should be renumbered as claims 27-53 because there were no claims 28-33 in the application as filed under 35 USC 371. For the purpose of clarity, the restriction requirement set forth below numbers the pending claims as 34-60. However, after election Applicant is required to renumber the claims appropriately.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 34-39, and 45, drawn to methods of treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising administering to a subject suffering from said disease an effective amount of a protein, peptide or anticaline, other than an antibody, that inhibits the activity of PRF1.

Group 2, claim(s) 34-39 and 45, drawn to methods of treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising

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administering to a subject suffering from said disease an effective amount of an antibody that inhibits the activity of PRF1.

Group 3, claim(s) 34-39 and 45, drawn to methods of treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising administering to a subject suffering from said disease an effective amount of a small molecule that inhibits the activity of PRF1.

Group 4, claims 34-40 and 45, drawn to methods of treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising administering to a subject suffering from said disease an effective amount of an aptamer that inhibits the activity of PRF1.

Group 5, claims 34-40 and 45, drawn to methods of treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising administering to a subject suffering from said disease an effective amount of an ribozyme or aptazyme that inhibits the activity of PRF1.

Group 6, claims 34-40 and 45, drawn to methods of treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising administering to a subject suffering from said disease an effective amount of an spiegelmer that inhibits the activity of PRF1.

Group 7, claims 34-42 and 45, drawn to methods of treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising administering to a subject suffering from said disease an effective amount of an antisense oligonucleotide that inhibits the activity of PRF1. Should Applicant elect this group, a further election of one of SEQ ID NOS: 4-13 is required. See below.

Group 8, claims 34-40 and 43-45, drawn to methods of treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising administering to a subject suffering from said disease an effective amount of an siRNA that inhibits the activity of PRF1.

Group 9, claims 46-50, 55, and 56, drawn to methods for identifying an agent suitable for treating a disease or pathological condition associated with dysregulation of the PI-3 kinase pathway, comprising contacting a test system comprising a protein having PRF1 activity with a composition comprising a candidate compound, and determining if PRF1 activity is reduced in the presence of said candidate compound.

Group 10, claims 51-54, drawn to methods for diagnosing a disease associated with a dysregulated PI-3 kinase pathway in a subject suspected of suffering from said disease, comprising measuring PRF1 activity in a sample obtained from said subject and

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comparing said activity with a control level of activity, wherein an increase in PRF1 activity indicates the presence of disease.

Group 11, claims 57-59 drawn to a composition comprising a protein, peptide or anticaline, other than an antibody, that inhibits the activity of PRF1.

Group 12, claims 57-59 drawn to a composition comprising an antibody that inhibits the activity of PRF1.

Group 13, claims 57-59 drawn to a composition comprising a small molecule that inhibits the activity of PRF1.

Group 14, claims 57-59 drawn to a composition comprising an aptamer that inhibits the activity of PRF1.

Group 15, claims 57-59 drawn to a composition comprising an aptazyme or ribozyme that inhibits the activity of PRF1.

Group 16, claims 57-59 drawn to a composition comprising a Spiegelmer that inhibits the activity of PRF1.

Group 17, claims 57-59 drawn to a composition comprising an antisense oligonucleotide that inhibits the activity of PRF1.

Group 18, claims 57-59 drawn to a composition comprising an siRNA that inhibits the activity of PRF1.

The inventions listed as Groups 1-18 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The technical feature linking the claimed inventions is PRF1, however according to the specification at page 10, lines 11-13 PRF1 was known in the prior art as GenBank Accession No. NP_061931, disclosed by Shoshani et al (Mol. Cell. Biol. 22 (7), 2283-2293 (2002), of record). Accordingly the technical feature linking the claimed invention is not a special technical feature under PCT Rule 13.2 because it fails to make a contribution over the prior art.

Note that the various methods of treatment have been restricted based upon the structural and functional characteristics of the therapeutic agent required in each method. This is consistent with the administrative instructions under the PCT wherein unity of invention is discussed in regard to Markush groups such as those set forth in claims 39, 40, and 42. Essentially, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural

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feature disclosed as being essential to that utility. The agents restricted from each other in groups 1-8 fail to pass this test because they share no substantial structural feature that is essential to the utility of inhibiting PRF1. For example, proteins, peptides, and anticlines that are not antibodies cannot share with antibodies any structural feature essential for inhibiting PRF1. Likewise no protein or peptide agent can share such a structural feature with any of the nucleic acid agents claimed. Aptamer inhibitors are considered to be structurally distinct from spiegelmers because they are non-superimposable mirror images with different characteristics, i.e. they are nuclease resistant, and bind to different (i.e. mirror image) targets. Aptamer inhibitors are considered to be structurally distinct from aptazymes because in the aptamer the inhibitory moiety is the aptamer, whereas in the aptazyme, the inhibitory moiety is a ribozyme to which the aptamer is fused. Ribozymes are considered to be structurally and functionally distinct from antisense and siRNAs due to the requirement for a catalytically active structure. Finally, antisense is distinct from siRNA in that siRNAs are double stranded RNAs, whereas antisense are single stranded nucleic acids.

Additionally, SEQ ID NOS: 4-13 are considered to lack unity of invention as well. Although these antisense sequences each target and modulate expression of PRF1, each antisense sequence has a unique nucleotide sequence, and so each antisense sequence targets a different and specific region of a PRF1 nucleic acid. As such SEQ ID NOS: 4-13 are not considered to constitute a proper genus, and are therefore subject to restriction. Note that this is not a species election. Should Applicant elect group y, a further election of one of SEQ ID NOS: 4-13 is required.

Finally note that 37 CFR 1.475(b) does not allow for the combination of different statutory classes of invention (e.g. combining products with methods of use or methods of making) wherein there is no special technical feature linking all of the claimed inventions.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central

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fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

A handwritten signature in black ink, appearing to read 'R. Schnizer', with a stylized, flowing script.

Richard Schnizer, Ph.D.
Primary Examiner
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